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ABSTRACT

This seventh in a series of eight modules for a course titled Quality Assurance Practices describes the key features of an audit system and offers practice in carrying out tasks of the technicians. The module follows a typical format that includes the following sections: (1) introduction, (2) module prerequisites, (3) objectives, (4) notes to instructor/student, (5) subject matter, (6) materials needed, (7) procedures, (8) data table, (9) reference materials, (10) test. (The course is one of fifteen technical courses for the second year of a two-year postsecondary curriculum in Nuclear Quality Assurance/Quality Control Technology.) (LRA)

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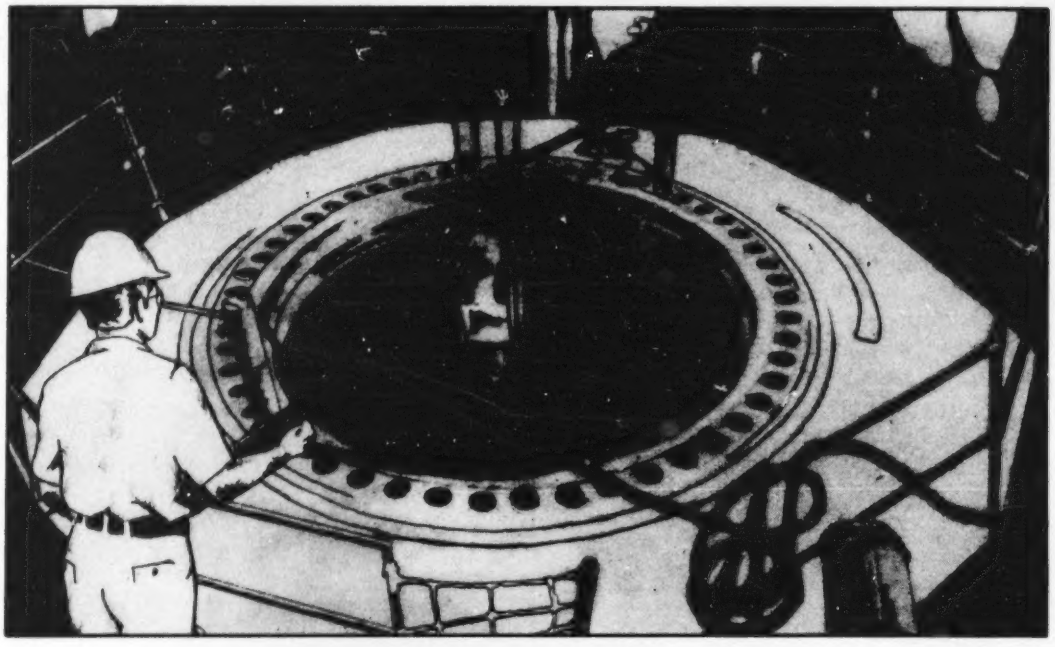
NUCLEAR TECHNOLOGY

COURSE 31 QUALITY ASSURANCE PRACTICES

MODULE 31-7 Auditing for Quality Assurance



CE 024 291

GENERAL PHYSICS CORPORATION
Columbia , Maryland

COURSE MODULES

COURSE 31 QUALITY ASSURANCE PRACTICES

Module 31-1	Overall Quality Assurance Program
Module 31-2	Vendor Qualification
Module 31-3	Receiving Inspection
Module 31-4	Identification, Storage and Handling of Components, Parts and Materials
Module 31-5	Non-Conforming Materials
Module 31-6	Certification and Qualification of Quality Control Inspectors
Module 31-7	Auditing for Quality Assurance
Module 31-8	Document Handling, Storage and Retrieval for Quality Assurance

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This module was prepared for General Physics Corporation by Jim Pritchard and John Espy, General Phusics Corporation.

GENERAL PHYSICS CORPORATION

1979

INTRODUCTION

The Nuclear QA/QC technician serves an important role in quality assurance audits. The technician assists in planning the overall audit system, prepares audit check lists, serves as an audit team member, assists in writing audit reports and reviewing replies thereto, and verifies the implementation of corrective action. This module describes the key features of an audit system and offers practice in carrying out these tasks of the technicians.

Quality Assurance Audits are required by 10CFR50, Appendix B. Even prior to the existance of this requirement, the value of audits was long recognized and audit systems were employed by many companies. If conducted properly, audits are a valuable management tool for increasing the effectiveness of a quality assurance program.

One can logically assume that managers strive to ensure that activities within their purview are carried out properly and efficiently. The manager establishes plans, resources and methods toward this purpose. How, then, can audits be useful? Two basic premises give insight to the answer: (1) A fresh look by persons not directly responsible for the activity can identify problems that were not previously sensed or considered worthy of action, and (2) Everything under control tends to go toward a state of uncontrol.

MODULE PREREQUISITES

The student shall have completed all previous modules of Course 31.

OBJECTIVES

Upon completion of this module, the student/trainee can:

1. Match codes and standards to audits.
2. State five objectives of the quality assurance audit system.
3. Describe the organizational relationship between auditors and the activity to be audited and offer rationale for the validity of this relationship.
4. Briefly describe the basis of qualification of auditors.
5. Briefly describe the basis of qualification of lead auditors.
6. Define internal and external audits.
7. State seven essential elements of the audit system and describe the basis for considering each element to be essential.
8. Describe how suppliers are selected for external audits.
9. Describe how subjects are selected for internal audit.
10. Name and discuss at least three factors considered in establishing the schedule for audits.
11. Name and discuss three major tasks associated with preparation for a specific audit.
12. Name and discuss three major tasks associated with performance of a specific audit.
13. Describe the types of information given by an audit report.
14. Describe the follow-up actions by the audited organization and the auditing organization.
15. Demonstrate the ability to plan for, conduct, and report an audit.

NOTES TO INSTRUCTOR

Advance preparation is required for the activities suggested by this module. For Procedure #1, copies of companies' procedures for quality assurance audit programs are necessary. Copies may be obtained from nearby nuclear industries such as utilities, construction contractors, and suppliers. For Procedure #2, local activities need to be selected to serve as audit subjects. Suggested activities are laboratory activities within the curriculum of the students/trainees.

SOURCE OF AUDIT REQUIREMENTS

Federal Regulation

Criterion XVIII of Appendix B to Title 10 Code of Federal Regulation Part 50 (10 CFR 50) requires that an audit program be established and implemented. This criterion reads as follows:

> A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with written procedures or check lists by appropriately trained personnel not having direct responsibilities to the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, shall be taken where indicated.

The Nuclear Regulatory Commission reviews applications for Construction Permits and Operating Licenses for nuclear power plants against this criterion. The applicant is required to describe the audit program employed by the utility and provisions for requiring audit programs by suppliers to the utility.

Regulatory Guides and Standards

Industrial societies have developed standards which give guidelines on methods for complying with Criterion XVIII of Appendix B to 10 CFR 50. The applicability of these standards is described by Regulatory Guides issued by the Nuclear Regulatory Commission. As illustrated in

Figure 31-7-1, different guides and standards apply to the Design and Construction Phases as compared to the Operations Phase.

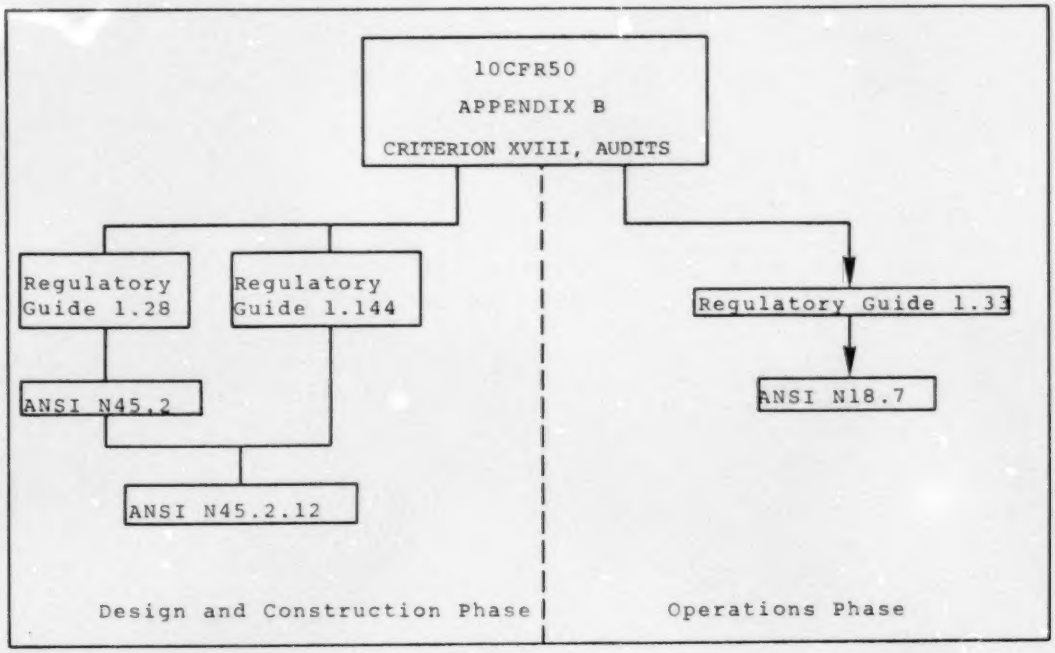


Figure 31-7-1. Regulations and Standards Audits

Design and Construction Phase Audit Requirements

NRC's Regulatory Guide 1.28 recognizes ANSI N45.2, "Quality Assurance Program Requirements for Nuclear Power Plants," as a satisfactory standard for the quality assurance program, including audits, for the Design and Construction Phase. Section 19 of ANSI N45.2 describes requirements for the audit program. A supplementary standard, ANSI N45.2.12 pertains specifically to audits and gives considerably more detailed requirements. NRC's Regulatory Guide 1.144 recognizes ANSI N45.2.12 as an

acceptable standard for quality assurance audits during the Design and Construction Phase and for audits of suppliers during the operations phase.

Operations Phase Audit Requirements

NRC's Regulatory Guide 1.33 recognizes ANSI N18.7, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants", as a satisfactory standard for the quality assurance program, including audits, for the Operations Phase. Section 4 of this ANSI N18.7 gives requirements for an audit program. NRC's Regulatory Guide 1.144 recommends application of ANSI N18.7 for audits at the power plant site during operation and permits application of ANSI N45.2.12 to audits of offsite suppliers.

While two standards apply to audits, there is so much similarity in their requirements that distinguishment between the standards is unnecessary. Therefore, this module covers the collective requirements of the two standards without attempting to distinguish between them.

AUDIT PROGRAMS

Definitions

The terms auditor, lead auditor, and audit are defined as follows:

- Auditor - Any individual who performs any portion of an audit, including Lead Auditors, technical specialists, and others such as management representatives and auditors-in-training.
- Lead Auditor - An individual qualified to organize and direct an audit, report audit findings, and evaluate corrective action.
- Audit - A documented activity performed in accordance

with written procedures or checklists to verify, by examination and evaluation of objective evidence, that applicable elements of the quality assurance program have been developed, documented, and effectively implemented in accordance with specified requirements. An audit should not be confused with surveillance or inspection for the sole purpose of process control or product acceptance.

Objectives of the Audit Program

Each company's audit program is described by written policies, plans, procedures or instructions. The written audit program description provides for the accomplishment of five objectives. These objectives of the audit program are:

- To determine that a Quality Assurance Program has been properly developed and is documented in accordance with all required regulations, codes and standards. This objective is aimed primarily toward Criterion II of 10CFR50, Appendix B, which requires a documented program that meets all applicable criteria of Appendix B.
- To ensure the documented Quality Assurance Program has been implemented by conducting examinations and evaluations of objective evidence. This objective is aimed primarily toward criterion I of 10CFR50, Appendix B, which requires each organization to execute the documented Quality Assurance Program.
- To determine the effectiveness of the Quality Assurance Program. This objective is aimed toward ensuring that the intent of 10CFR50, Appendix B, is met, i.e., that an adequate Quality Assurance Program exists.
- To identify any deficiencies or nonconformances of

the Quality Assurance Program. This objective sometimes results in auditors being labeled as the "bad person" or "spy". However, for improvements to be made, deficiencies must be identified. In this objective, the term deficiency refers to failure to develop, document or implement any portion of the Quality Assurance Program. The term nonconformance refers to anything that renders the quality of plant hardware items as unacceptable or unknown. These two terms are used to distinguish administrative problems (deficiency) from technical problems (nonconformance). A deficiency can be a nonconformance when the failure of the Quality Assurance Program causes an action that is detrimental to hardware quality or omits an action that is needed to determine hardware quality.

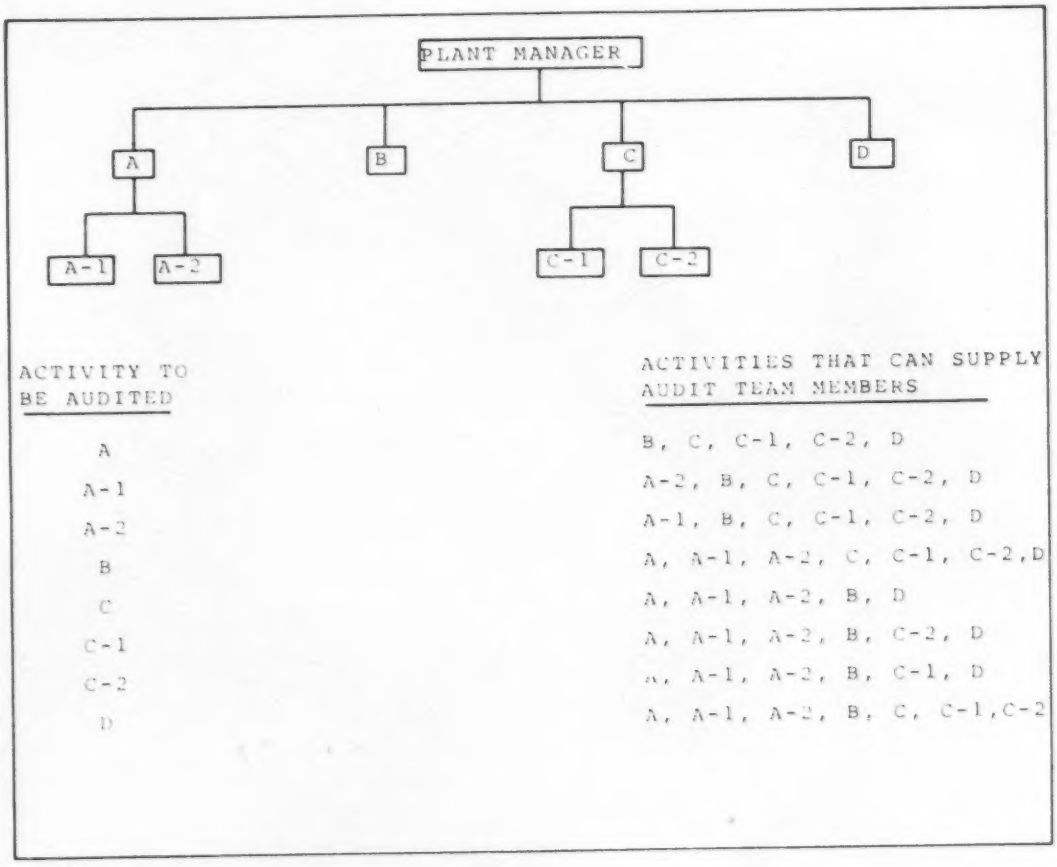
- To ensure any deficiencies in a Quality Assurance Program are corrected. This objective is the logical extention of the prior objective. It does not pertain specifically to nonconformances because any nonconformance noted would be handled via the nonconforming material control system described by Module 31-5 of this course. The nonconforming material control system is subject to audits and such audits can be relied upon to ensure that nonconformances are properly corrected.

Independence of Audit Personnel

All persons selected to serve on quality assurance audit teams are selected and assigned to ensure that each team member does not have direct responsibility for the performance of the activities which they will audit. Further, persons having direct responsibility for the performance of the activities being audited can not be in-

volved in the selection of audit team personnel. Direct responsibility refers to the performing, supervising and managing an activity that is to be audited. Independence from the activity to be audited ensures better objectivity in that the auditor provides a "fresh look" and does not have to defend the practices employed within the activity.

To illustrate independence of auditors, Figure 31-7-2 identifies possible combinations of audit team members for a hypothetical organization.



ACTIVITY TO BE AUDITED	ACTIVITIES THAT CAN SUPPLY AUDIT TEAM MEMBERS
A	B, C, C-1, C-2, D
A-1	A-2, B, C, C-1, C-2, D
A-2	A-1, B, C, C-1, C-2, D
B	A, A-1, A-2, C, C-1, C-2,D
C	A, A-1, A-2, B, D
C-1	A, A-1, A-2, B, C-2, D
C-2	A, A-1, A-2, B, C-1, D
D	A, A-1, A-2, B, C, C-1,C-2

Figure 3i-7-2. Audit Team Selection

Qualification of Auditors and Lead Auditors

Each company is responsible for establishing the qualification requirements for audits. Such qualification requirements ensure that personnel selected for auditors and lead auditors have the experience and training commensurate with the scope, complexity and special nature of the activities to be audited. Put simply, auditors should be knowledgable on the audit subject and experienced as auditors.

Auditors are qualified by training and on-the-job experience. Training of auditors consists of (1) orientation training on quality assurance systems and (2) specialized training in auditing techniques. The orientation-training provides a working knowledge and understanding of quality assurance regulations and standards and the company's quality assurance program. Specialized training provides knowledge and develops skills in auditing techniques. Knowledge and understanding are provided on audit objectives, essential elements, and procedures for planning, performing, and reporting of quality assurance audits. Skills are developed in examining, questioning, evaluating, documenting, and closing out specific audit items. On-the-job experience consists of audit performance under the direct supervision of a lead auditor. Training, guidance, and counseling is provided by the lead auditor on planning, performing, reporting and followup actions associated with audits.

Qualification of lead auditors is based on (1) education and experience, (2) communications skills, (3) training, (4) audit participation, and (5) examination. Each of these are described as follows:

- Education and experience - ANSI N45.2.23 specifies a point system for education and experience. Point credits are allotted for level of education; technical experience in engineering, manufacturing,

construction, operation, or maintenance; certificates of competency in engineering, science, or quality assurance specialities which are issued and approved by state agency or national professional or technical society; and performance within the company's organization. A minimum of 10 points total from these categories is necessary for qualification.

- Communications skill - Oral and written communications skills are extremely important for the lead auditor in both directing the audit and communicating with the audited organization. The company is required to attest in writing that their lead auditors possess effective oral and written communications skills.
- Training - Lead auditor training consists of five parts: (1) regulations and standards, (2) structure of quality assurance program, (3) audit planning, (4) auditing techniques, and (5) on-the-job training. Training provisions for these five areas are listed in Table 31-7-1.
- Audit participation - The prospective lead auditor is required to have participated in at least five quality assurance audits within the three years prior to the date of qualification. At least one of the audits must be a nuclear quality assurance audit and performed within one year prior to the date of qualification.
- Examination - The prospective lead auditor must pass an examination which evaluates the candidate's comprehension of and ability to apply the body of information addressed by the five areas of training. The examination may be oral, written, practical or combination thereof.

Table 31-7-1

Training of Lead Auditors	
Subject	Objectives
Regulations and Standards	To provide a knowledge and understanding of quality assurance regulations and standards.
Structure of Quality Assurance Programs	To provide a knowledge and understanding of quality assurance programs as a whole and applicable elements such as organization; design control; procurement document control; procedures and drawings; document control; control of purchased materials, equipment, and services; identification and control of materials, parts, and components; control of special processes; test control; control of measuring and test equipment; handling, storage, and shipping; inspection, test and operating status; nonconforming materials, parts, or components; corrective action; quality assurance records; audits; and quality information feedback.
Audit Planning	To provide knowledge and develop skills in audit planning associated with scheduling, preparation, performance, reporting, and followup of audits.
Auditing Techniques	To develop skills in audit techniques of examining, questioning, evaluating, reporting, followup, and closeout.
On-the-Job	To provide practical experience in audit planning and auditing techniques.

Types of Audits

There are two basic types of audits: internal and external. Internal audits are audits of those portions of an organization's QA program retained under its direct control and within its organizational structure. External audits are audits of those portions of an organization's QA program not retained under its direct control and not within its organizational structure. In most cases. internal audits are internal to a company and external audits address suppliers to that company. However, the definitions of these audits also pertain to different organizational entities within a parent company.

External Audits

External audits are applied to suppliers. As described in Module 31-1, a pyramid of hundreds of suppliers can be involved in the design, construction and operation of a nuclear power plant. Each company that contracts for items and services establishes an external audit program to evaluate the quality assurance program employed by the subcontractor. Module 31-1 pointed out that the extent of quality assurance requirements imposed on a subcontractor is proportional to the significance of the contracted item or service on safe plant operations. Therefore, the extent of auditing of subcontractors also varies on the same basis. Unless the supplier's items or services are accepted solely by receiving inspection, each supplier is audited either annually or triannually.

External audits are performed prior to placement of a contract (preaward) or after placement of a contract (postaward).

The preaward audit is performed when there is no or little prior experience with the subcontractor and the contract to be placed involves items or services that are

very important to safe plant operation. This audit determines if the subcontractor is capable of delivering quality items or services. Placement of the contract is contingent on the findings of the preaward audit.

The postaward audit is performed to determine that the subcontractor is producing quality items or services. This type of audit is needed for those items and services that are too complex to determine quality by inspection alone. Such items and services typically include those by nuclear steam system suppliers, architect-engineers, and component suppliers described in Module 31-1. The other types of suppliers described in Module 31-1 may be audited dependent on the significance of their product to safe plant operation.

Internal Audits

Internal audits are conducted by an organization to determine that its own quality assurance program is adequate and effective. The internal audit program addresses each applicable criteria of 10CFR50, Appendix B and other applicable regulatory requirements. The applicant for construction permits and operating licenses for nuclear power plants and all tiers of contractors to the applicant can be expected to implement an internal audit program.

Essential Elements of the Audit System

There are seven essential elements of a quality assurance audit system. Audit systems which contain these essential elements have little difficulty in meeting the five objectives described earlier. These essential elements are:

- A management policy statement which establishes organizational independence and authority of the auditors and commits the organization to an audit

system meeting the requirements of governing regulations and standards.

- Commitment to the necessary staffing, funding and facilities to implement the audit system.
- Identification of responsibilities for the audit system.
- Provisions for audit teams to have reasonable and timely access to the facilities, documents and personnel necessary in the planning and performance of audits.
- Provisions for reporting on the effectiveness of the Quality Assurance Program to the responsible management of both the audited and auditing organizations.
- Provisions for access by audit teams to levels of management of both the auditing and audited organizations that have responsibility and authority to assure corrective action.
- Provision for the verification of effective corrective actions on a timely basis.

The first essential element, management policy statement, is issued by a senior level of management (President or Vice-President). The policy statement is normally the introductory part of the audit system procedure although it could be issued separately. This statement serves to announce to the entire organization that the company desires to have an effective audit system and that all departments are expected to support the audit system.

The second essential element, commitment to resources, takes into consideration that audits cost time and money and do not directly produce product. It is an overhead cost. Its worth is in its ability to detect and correct conditions that are likely to cause nonconformances. Since nonconformances represent losses, including

high dollar losses, it is possible that prevention of a single, large cost nonconformance will pay for a year's worth of audits. However, it takes effective audits to achieve overall cost savings. This essential element is based on the need to invest labor hours, funding and facilities to make it possible for effective audits to be performed. It is also based on the premise that a definite expenditure for audits is warranted just to obtain confidence in the Quality Assurance Program.

The third essential element, identification of responsibilities, delineates the authorities, responsibilities and organizational independence for each portion of the audit system. Most companies assign overall audit responsibility to their Quality Assurance Managers. This essential element gives to the manager the authority to have unimpeded access to other organizational entities to audit their portions of the Quality Assurance Program. It also charges audited organizations to develop effective corrective action on audit findings.

The fourth essential element, reasonable and timely access, is contained in procedures and contracts. For internal audits, provisions for access is normally included in the management policy statement given as the first essential element. For external audits, provisions are placed in the procurement documents for reasonable and timely access to the subcontractor's facilities, records and personnel. This essential element is based on the need for full and unimpeded discourse of information to permit performance of a meaningful audit.

The fifth essential element, reporting, pertains to level of reporting and nature of the report. Managers are responsible for effective implementation of quality assurance activities and have the authority to change or add methods of implementation. For this reason, this

essential element provides for reporting audit results to a level within the company who can initiate actions to improve the Quality Assurance Program. Also, this essential element authorizes the lead auditor to report on the effectiveness of the Quality Assurance Program based on audit findings.

The sixth essential element, access to management is important during the performance of an audit. It permits the audit team to discuss with appropriate levels of management the approach, progress and results of the audit. It helps ensure obtaining all relevant information because management is aware of all sources of information which may be of interest to the auditors. Also it gives immediate reaction to audit findings which helps the lead auditor to report findings in proper perspective. Therefore, this essential element provides for two way communication with responsible persons such that performance of audits and understanding and correction of audit findings are improved.

The seventh essential element, verification of corrective action, gives authority and responsibility to the auditing organization to confirm that effective corrective action has been taken. For corrective action to be totally effective, it must be timely to avoid the generation of nonconformances in the interval between detection of a deficiency and implementation of corrective action. This essential element ensures that the same independent review which found deficiencies is also applied toward corrective actions.

AUDIT SYSTEM PLANNING AND SCHEDULING

Scope of Planning

The audit system and each individual audit require planning in order to provide for effective results. This section describes planning of the audit system. A later section of this module describes planning of an individual audit.

The individual assigned the overall responsibility for the audit system (usually the Quality Assurance Manager) ensures adequate planning of the audit system. Such planning provides for determination of (1) what to audit, (2) approximately when to audit, (3) who will audit and (4) how audits are generally performed. The planning results in a written procedure which describes these determinations as well as assigning responsibilities for continuously making these determinations.

What to Audit

There is an axiom within quality assurance circles that states "if it is required, it should be audited". This axiom applies to the determination of what to audit but it is tempered by the resources allocated to the audit system. There are so many requirements that it is simply impractical to audit all requirements. Therefore, those requirements most important to safe operation of the nuclear power plant receive highest priority. The audit system procedure assigns responsibility for determining what to audit.

For external audits, determination of what to audit culminates in a listing of suppliers to be audited. This listing is not static. As contracts are placed with suppliers not on the listing, a determination is made to

add or not add the supplier. Suppliers placed on the listing meet one or more of the following characteristics:

- Supplier of complex product or services
- Source and receiving inspection results indicate that the supplier has a poor or marginal quality assurance program
- Little prior knowledge of supplier performance
- Previous audit indicated need for followup audit.

For internal audits, determination of what to audit results in a listing of audit subjects by (1) quality assurance criteria or (2) organizational department. In the former case, all of the applicable criteria of Appendix B to 10 CFR 50 serve as the audit subject list. Some organizations use the applicable eighteen criteria verbatim as the audit subject listing while others subdivide several of the criteria. Either approach results in auditing all departments within the organization who have activities within the criteria selected for audit. This offers the advantage of easily auditing the interfaces among various departments. It has the disadvantage of more frequent audits of a given department because most departments have responsibilities under many of the eighteen criteria. In the second case, a listing of each department having quality assurance activities comprises the audit subject listing. In this case, an audit of a department covers all criteria of Appendix B to 10 CFR 50 that fall within the responsibilities of the audited department. This offers the advantage of less frequent audits of a given department. It has the disadvantage of large potential for not effectively auditing the interfaces between the audited department and other departments.

When to Audit

The audit system procedure assigns responsibility for maintaining a schedule of audits to be conducted. The schedule may project those audits planned for the next six months, next year or next several years. The schedule is not static but is adjusted as the need arises to identify when audits will be performed.

For both internal and external audits, determination of when to audit gives consideration to unique functions within the audit subject that tend to dictate when to audit. In some cases, it doesn't matter when the audit is performed. However, the following factors may dictate the audit schedule; these are considered in development and maintenance of the schedule for both internal and external audits:

- Duration of the Work Effort - If the subject to be audited is of short term effort, it must be audited early during the life of the effort.
- First of a Kind Activity - If the audit subject includes activities that are being done for the first time, it is wise to audit that subject at the onset of the first of a kind activity. This is based on historical data which indicate that more problems are associated in first-time performance of an activity than in subsequent performance of the same activity.
- Significant Changes in Organizational Responsibilities - While an activity may have been performed many times, if another organization or department is assigned responsibility for the activity, some problems can be expected to occur. Shortly after significant changes in organizational responsibilities, an audit should be conducted.
- Critical State of Activity - Within many activities there are certain scheduled tasks that are extremely

important to the successful accomplishment of the activity. When this is known, it is best to schedule the audit to coincide with these important tasks.

- Elapsed time since previous audit - Regulatory requirements require that certain audits be conducted annually or triennially. The audit schedule must provide for compliance with such commitments to the NRC.

Who Will Audit

The audit system procedure can identify audit team members in several different ways. Two ways are most common. One is the requirement to list the lead auditor and each auditor on the audit schedule. The other is identification of a lead auditor for each audit subject and requirement for such lead auditors to select an appropriate number of auditors. In either case, persons independent of the subject to be audited are selected as discussed earlier in this module.

Selection of persons to comprise the audit team should ensure that major skills that will be needed are represented. One cannot readily audit an unfamiliar subject. Therefore, the skills associated with the audit subject should be reviewed and individuals should be selected based on their possession of these skills. As previously mentioned, both lead auditors and auditors must be qualified.

How Audits Are Generally Performed

The audit system procedure gives policies for planning audits. These policies provide for (1) advance arrangements with the organization to be audited, (2) advance preparation by the audit team, (3) responsibilities for conduct of the audit, (4) reporting the audit and (5) followup on corrective action. Individual audits are planned within

these policies which typically are as follows:

- Audit team membership is finalized four weeks prior to the audit date to permit adequate preparation.
- Arrangements for the audit are made three weeks in advance with the organization(s) to be audited.
- Check lists are used as guidance during each audit.
- The lead auditor chairs entrance and exit meetings with the audited organization(s). These meetings arrange for specific conduct of the audit and orally present the audit findings.
- The lead auditor issues the audit report within two weeks of completion of an audit.
- Each audit report is distributed to the senior manager of the audited organization(s), the company president, the quality assurance manager and others as determined by the lead auditor.
- The lead auditor assures adequate corrective action on audit findings and schedules follow-up audits as necessary.

AUDIT IMPLEMENTATION

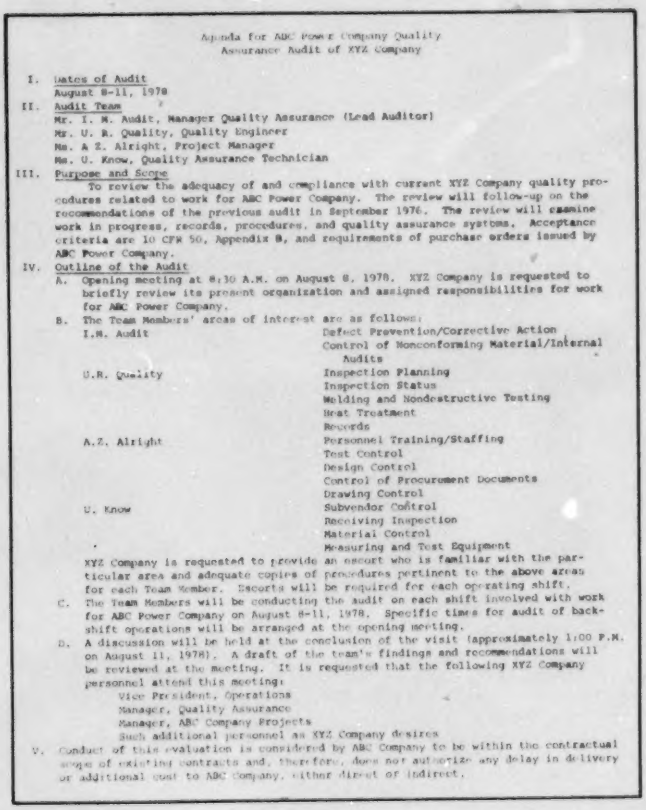
Scope

Within the policies established by the audit system procedure, each individual audit involves the following activities toward ensuring that an effective audit is performed. The four activities are (1) preparation, (2) performance, (3) reporting, and (4) corrective action follow-up.

Preparation

Preparation of an audit involves establishing an audit plan, preparing the audit team and making arrangements with the organization(s) to be audited. The lead auditor normally has overall responsibility for preparation although each team member is usually given specific preparatory tasks. Three major tasks are involved: (1) development of a written audit plan, (2) selection and orientation of the audit team and (3) notification of the organization to be audited:

- Written Audit Plan - An individual written plan is developed for each audit to be conducted. If the subject is being audited for the first time, a new plan must be developed. If the subject has previously been audited, the prior plan is updated as necessary. The plan covers the scope of the audit, the requirements governing the audit subject, the activities to be audited, organizations to be notified of the impending audit, audit dates, and check lists. All this planning can be accomplished by the preparation of an audit agenda as illustrated by Figure 31-7-3 and audit check lists as illustrated in Figure 31-7-4.



Agenda for ABC Power Company Quality
Assurance Audit of XYZ Company

I. Dates of Audit
August 8-11, 1978

II. Audit Team
Mr. I. M. Audit, Manager Quality Assurance (Lead Auditor)
Mr. U. R. Quality, Quality Engineer
Ms. A Z. Alright, Project Manager
Ms. U. Know, Quality Assurance Technician

III. Purpose and Scope
To review the adequacy of and compliance with current XYZ Company quality procedures related to work for ABC Power Company. The review will follow-up on the recommendations of the previous audit in September 1976. The review will examine work in progress, records, procedures, and quality assurance systems. Acceptance criteria are 10 CFR 50, Appendix B, and requirements of purchase orders issued by ABC Power Company.

IV. Outline of the Audit
A. Opening meeting at 8:30 A.M. on August 8, 1978. XYZ Company is requested to briefly review its present organization and assigned responsibilities for work for ABC Power Company.
B. The Team Members' areas of interest are as follows:

I.M. Audit	Defect Prevention/Corrective Action
	Control of Nonconforming Material/Internal Audits
U.R. Quality	Inspection Planning
	Inspection Status
	Welding and Nondestructive Testing
	Heat Treatment
	Records
A.Z. Alright	Personnel Training/Staffing
	Test Control
	Design Control
	Control of Procurement Documents
	Drawing Control
U. Know	Subvendor Control
	Receiving Inspection
	Material Control
	Measuring and Test Equipment

XYZ Company is requested to provide an escort who is familiar with the particular area and adequate copies of procedures pertinent to the above areas for each Team Member. Escorts will be required for each operating shift.
C. The Team Members will be conducting the audit on each shift involved with work for ABC Power Company on August 8-11, 1978. Specific times for audit of backshift operations will be arranged at the opening meeting.
D. A discussion will be held at the conclusion of the visit (approximately 1:00 P.M. on August 11, 1978). A draft of the team's findings and recommendations will be reviewed at the meeting. It is requested that the following XYZ Company personnel attend this meeting:
Vice President, Operations
Manager, Quality Assurance
Manager, ABC Company Projects
Such additional personnel as XYZ Company desires

V. Conduct of this evaluation is considered by ABC Company to be within the contractual scope of existing contracts and, therefore, does not authorize any delay in delivery or additional cost to ABC Company, either direct or indirect.

Figure 31-7-3. Sample Audit Agenda

Referring to The Sample Agenda, most plans for the audit are identified by the agenda. It identifies the scope of the audit and the major codes and standards that govern the audit subjects. It lists team members and activities to be audited by each team member. It identifies key personnel of the organization to be audited and specific dates and times for conduct of the audit.

The Lead Auditor normally consults with team members for assistance in preparing the audit agenda. During this time, individual team member assignments are finalized. Also, suggestions are made for items to be studied prior to the audit and assignments are made for preparing (or updating) audit check lists.

Check lists comprize the second portion of the written planning for a specific audit. Check lists guide the auditor during performance of the audit and help to ensure that major items are not overlooked. No matter how knowledgeable one may be on a given subject, the rapid pace of an audit in progress makes it easy to make false starts or to omit important questions. Use of a checklist can avoid these pitfalls.

There is no universally accepted format and content for checklists. Instead, the worth of a checklist is measured by its value to the user. However, in general, checklists should always include all essential elements of the subject to be audited. For example, if one were to audit a company's internal audit system, the checklist would cover all seven essential elements of an audit system described earlier in this module. In preparing specific

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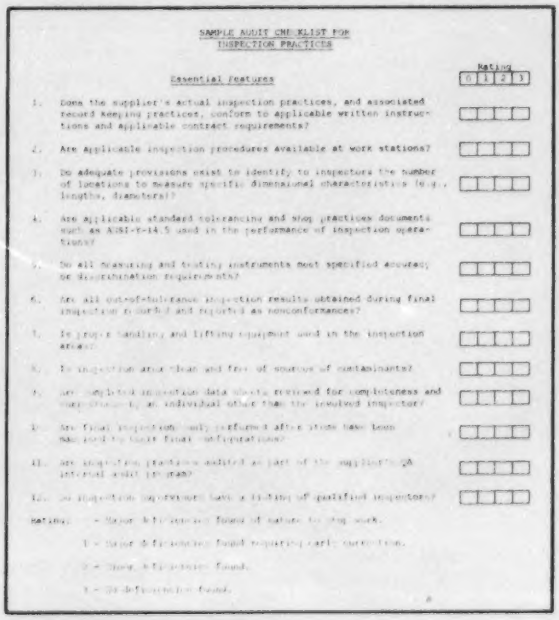

SAMPLE AUDIT CHECKLIST FOR
INSPECTION PRACTICES

Essential Features	Rating 0 1 2 3
1. Does the supplier's actual inspection practices, and associated record keeping practices, conform to applicable written instructions and applicable contract requirements?	
2. Are applicable inspection procedures available at work stations?	
3. Do adequate provisions exist to identify, to inspectors the number of locations to measure specific dimensional characteristics (e.g., lengths, diameters)?	
4. Are applicable standard tolerancing and shop practices documents such as ASSI-Y-14.5 used in the performance of inspection operations?	
5. Do all measuring and testing instruments meet specified accuracy or discrimination requirements?	
6. Are all out-of-tolerance inspection results obtained during final inspection recorded and reported as nonconformances?	
7. Is proper handling and lifting equipment used in the inspection areas?	
8. Is inspection area clean and free of sources of contaminants?	
9. Are completed inspection data sheets reviewed for completeness and correctness by an individual other than the involved inspector?	
10. Are final inspection and performance after steps have been established to check final configurations?	
11. Are inspection practices audited as part of the supplier's QA internal audit program?	
12. Do inspection supervisors have a listing of qualified inspectors?	

Rating: 0 = Major deficiencies found of nature to stop work.
1 = Major deficiencies found requiring early correction.
2 = Some deficiencies found.
3 = No deficiencies found.

Figure 31-7-4. Sample Audit Check List

checks to be made for each essential element, the preparer would consider (1) requirements which must be met by the organization(s) to be audited, (2) sequence of checks, and (3) known or suspected problem areas.

- Audit team selection and orientation - The persons selected to serve on an audit team are selected with consideration given to (1) special abilities, (2) specialized technical training, (3) prior audit experience, (4) personnel characteristics, and (5) education. Selection of the lead auditor is normally made by the Quality Assurance Manager. The lead auditor, in turn, normally has responsibilities to (1) select, organize and lead the team, (2) make advance arrangements with the organization(s) to be audited, (3) plan for the conduct of the audit (normally with assistance from each team member), (4) be sure each team member understands team assignments and the overall approach, (5) represent the team during conduct of the audit, (6) ensure adequate progress and effectiveness of the audit team, (7) ensure that audit findings are valid and presented to the audited organization(s), (8) issue the audit report, and (9) ensure adequate corrective action and follow-up. Orientation for the team members by the Team Leader ensures that each team member is properly prepared prior to the audit. The orientation covers such areas as the applicable procedures, codes, policies, instructions and regulatory requirements. Also, prior audit reports of the same organization(s) and other performance data (e.g., inspection and test records) are reviewed to gain insight on suspected problem areas that should receive emphasis. Finally, attention is given to organizational structure,

interfaces and responsibilities of the activity to be audited. The end result is that each team member has a complete audit plan, an understanding of the specific assignments and a foreknowledge of who to contact during conduct of the audit. Such orientation ensures that the audit is conducted in an orderly and efficient manner.

- Notification of Impending Audit - Notification of the organization(s) that an audit is to be conducted is normally made by a letter which forwards an audit agenda or describes the scope of the audit, the lead auditor, and the dates of the audit. Specific arrangements for audit dates and focal points for communication are normally made by telephone and then confirmed by the letter.

Performance of an Audit

The performance section of an audit begins with arrival of the team and ends with their departure. It consists of (1) pre-audit conference, (2) audit process and (3) post-audit conference.

The pre-audit conference is a short meeting (e.g., one hour or less) upon initial arrival of the team. It is held with responsible management of the organization(s) being audited. This meeting reviews the audit agenda and specifically covers introduction of personnel, scope of the audit, presentation of the audit plan, establishment of contacts for team members, review of the audit sequence, plans for the post-audit conference, and proper channels of communications during conduct of the audit.

The audit process begins upon completion of the pre-audit meeting. The value of the planning for the audit quickly becomes apparent as conduct of the audit progresses. Specific techniques used tend to vary from one auditor to another

but in general the following techniques should be employed:

- Use check lists as a guide.
- If not already familiar with the various sites to be visited during the audit, tour briefly the sites to gain familiarity.
- Upon arrival at an area, look around and make a cursory review to see if everything appears to be in order before making the specific planned checks. Anything that appears to be unusual or out of order should be included in the samples selected for audit.
- Ensure the sequence of checks would uncover a deficiency if one exists. For example, if calibration of gages in use is the evaluation characteristic, the evaluation would not start with the gage calibration laboratory. Instead, gages on the floor would first be selected.
- Verify statements by checking objective evidence.
- Assess as checks are made, i.e., measure the value of discrete steps in terms of the requirement or organization's procedure.
- If a discrepancy appears to exist, pursue the indications to determine positively its existence and its extent.
- Have the organization confirm the existence of a deficiency. This avoids surprises later on and also permits the organization to point out any additional information that should be considered.
- Consider the potential causes of deficiencies found and pursue indicators of problems to determine their source.
- Deviate from the plan if there are indicators of problems outside the scope of the plan. (NOTE: In these instances, the auditor may elect to confirm the existence of a problem without determining its full

scope and request the organization to evaluate it and report results.)

- Perodically compare the plan against progress to determine that all areas are being audited.
- Analyze findings to determine if other or broader problems are indicated and what additional checks need to be made to confirm it. When a number of similar deficiencies are found, the organization's planning, training, supervision and internal audits are suspect.
- Ask the organization to correct minor deficiencies as you go; avoid making a management issue of minor deficiency.
- Confirm the individual who is supplying information is responsible for the item being evaluated; if not, determine who is and go to that person. People tend to answer questions on subjects for which they are not responsible; however, the auditor cannot base decisions on answers from people who are not responsible.
- Observe actual work practices, compare requirements with work practices.
- Request demonstrations if work practices cannot be observed.
- Ensure that a representative sample of evidence is selected.

In addition to the foregoing, any conditions requiring immediate corrective action are promptly brought to the attention of the manager of the audited organization. This is because the audited organization(s) is (are) responsible for identifying cause(s) and effects(s) of deficiencies. The extent of corrective action required is dependent on such causes and effects. The audit team must consider the poten-

tial for nonconformances to keep occurring until corrective action is taken. For significant findings, prompt identification to management permits corrective action to be initiated while the audit remains in progress.

Another general technique is to give specific attention to corrective actions taken in response to previous audits. It does little good to find new deficiencies if previously reported deficiencies have not been corrected.

The post-audit conference is held at the completion of the audit and prior to the team's departure. This meeting is with the audited organization's management and audit findings are presented. The lead auditor normally chairs this meeting. Audit results are reviewed and any misunderstandings are clarified. Finally, an understanding is reached on remaining actions including target dates for issuing the audit report and for replying to the audit findings.

Reporting of Audits

As soon as possible after completion of an audit and at least within 30 days, a written audit report is distributed to all responsible management of both the audited and auditing organizations. The report contains all important information concerning the audit such that reference to other documents is unnecessary. In this regard the report identifies:

- Team members and the key personnel contacted during the audit.
- The scope of the audit.
- A summary of the audit results, including an evaluation statement regarding the effectiveness of the Q.A. program that was audited.
- A detailed description of each Q.A program deficiency in sufficient detail to ensure corrective action can be carried out.

- Recommendations for correcting program deficiencies or improving the Q.A. program.
- Signature of the lead auditor.

While the format of an audit report varies from one organization to another, Figure 31-7-5 illustrates a common format. The report is typically forwarded by letter to senior management of the audited organization. A sample forwarding letter is illustrated in Figure 31-7-6.

Follow-up

After reporting an audit, follow-up action is required by two parties. First, management of the audited organization reviews and investigates all adverse findings to determine and schedule the appropriate corrective action. The corrective action must correct specific deficiencies as well as correct the condition that caused the deficiency. The corrective actions taken or planned are described in a reply to the audit report. In the event that planned corrective actions cannot be completed within a reasonable time frame, e.g., 30 days, the reply lists scheduled dates for completion of the corrected action.

The second follow-up is performed by the lead auditor or persons designated by management of the auditing organization. This follow-up initially evaluates the adequacy of the response to the audit report. If adequate corrective action is described, the response is accepted. If not, comments on the reply are forwarded for consideration by the audited organization. Once satisfactory corrective actions have been identified and scheduled for each deficiency or area of nonconformance, the lead auditor schedules an activity to verify that corrective actions are completed on schedule. This verification may be accomplished by written communications, inspections and surveillance, or re-audits.

AUDIT REPORT

I. Place:
(organization or site audited)

II. Dates:
(dates of the audit)

III. Audit Team:
(name, title and organization of each auditor including identification of who served as the lead auditor.)

IV. Personnel Contacted:
(name, title and organization of key personnel contacted during conduct of the audit.)

V. Summary and Conclusions:
(concise description of the audit, its results and major conclusions.)

A. Finding #1:
(concise statement of deficiency)

B. Discussion:
(details which support the existence of the deficiency)

C. Recommendation:
(action considered necessary to correct the deficiency.)

Figure 31-7-5. Sample Report Format

Letter to Vice President, Operations, XYZ Company

Dear Mr. Vice President"

This letter forwards the report of the quality assurance audit conducted by ABC Power Company on August 8 - 11, 1978.

The enclosed report identifies that, in general, XYZ Company has implemented a satisfactory quality assurance program. However, one major area of concern was noted. The Team found that records indicate that 6 of 23 tests have been conducted by unqualified personnel. Of the components represented by these 6 tests, two have been delivered to ABC Power Company. You are requested to promptly advise ABC Power Company of the actions taken to correct this serious matter.

In addition to the above major concern, the Team noted several deficiencies in need of correction. These are described by the enclosed report. I would appreciate a reply within 30 days describing the actions taken or to be taken on each of the Team's findings.

I appreciate the cooperation and support extended to the audit team.

Very truly yours,

Vice President, Power Generation
ABC Power Company

Figure 31-7-6. Sample Audit Report Transmittal Letter

SUMMARY

The following summarizes the major points developed in this module on auditing for quality assurance.

____ Nuclear utilities are required by 10 CFR 50, Appendix B to have a program of internal and external audits and to require their suppliers to have similar audit programs commensurate with the importance of suppliers' items and services to safe plant operation.

____ ANSI N45.2 provides requirements for the QA program for Design and Construction including audit program requirements; ANSI N18.7 provides requirements for the QA program for operation including audit program requirements.

____ ANSI N45.2.12 provides detailed requirements for an audit program.

____ The five objectives of the audit program are to (1) determine that an adequate QA program is developed and documented, (2) ensure implementation of the QA program, (3) determine effectiveness of the QA program, (4) identify deficiencies and nonconformances, and (5) ensure correction of deficiencies.

____ Auditors cannot have direct responsibility for the activities which they audit.

____ Auditors are qualified based on (1) orientation training, (2) specialized training, and (3) on the job experience.

____ Lead auditors are qualified based on (1) education and experience, (2) communication skill, (3) training, (4) audit participation, and (5) examination.

____ Internal audits are audits of those portions of an organization's QA program retained under its direct control and within its organizational structure.

____ External audits are preaward or post award audits of those portions of an organization's QA program not retained under its direct control and not within its organizational structure.

____ The seven essential elements of an audit system are (1) management policy statement which establishes independence and authority of auditors and commits the organization to an audit system, (2) commitment to necessary staffing, funding, and facilities, (3) identification of responsibilities, (4) provisions for reasonable and timely access by audit teams to facilities, documents, and personnel, (5) provisions for reporting on the effectiveness of the QA program to responsible management, (6) provision for audit team access to responsible levels of management, and (7) provision for verification of corrective action.

____ Suppliers are selected for external audit based on importance of their items and services to safe plant operation giving consideration to (1) complexity of items or services, (2) performance data for the supplier, (3) prior knowledge of supplier performance, and (4) need for follow-up audits.

____ Subjects for internal audit are selected by either (1) QA criteria applicable to the organization or (2) departments within the organization who have QA responsibilities.

____ Factors considered in scheduling audits are (1) duration of work effort, (2) first of kind activities, (3) significant changes in organizational responsibilities, (4) critical stages of activity, and (5) elapsed time since previous audit.

____ Team members are selected to obtain qualified auditors who possess skills appropriate to the activity to be audited.

____ Policies for performing audits provide for (1) advance arrangements with the organization to be audited, (2) advance preparation by the audit team, (3) responsibilities for conduct of the audit, (4) reporting the audit, and (5) following-up on corrective action.

____ Planning for a specific audit involves (1) preparation, (2) performance, (3) reporting, and (4) corrective action follow-up.

____ Preparation for a specific audit involves (1) development of a written audit plan, (2) selection and orientation of the audit team, and (3) notification of the organization to be audited.

____ Performance of a specific audit involves (1) pre-audit conference, (2) audit process, and (3) post-audit conference.

____ Reporting involves preparation and issuance of an audit report which identifies (1) team member and key personnel contacted, (2) scope of the audit, (3) summary of audit results including statement on the effectiveness of the QA program, (4) detailed description of deficiencies found, (5) recommendations for corrective action and (6) signature of lead auditor.

____ Follow-up involves (1) determination of corrective actions and reply to audit report by the audited organization and (2) verification of timely implementation of corrective action by the auditing organization.

EXERCISES

The following exercises serve to reinforce the material presented in this module.

1. Obtain a company's procedure for performing QA audits from your instructor. Follow the instructions given in the Procedures section of this module to prepare a report of your evaluation of this procedure.
2. Perform an audit of a subject assigned by your instructor following the instructions given in the Procedures section of this module.
3. Briefly discuss the objectives of the quality assurance audit system.
4. Discuss the basis upon which QA auditors are qualified.
5. Explain the difference between internal and external audits.
6. What are the essential elements of the audit system?
7. List three factors considered in establishing the scheduling for audits.
8. What are some of the types of information presented in an audit report?
9. Discuss briefly the follow-up actions by the audited organization and the auditing organization.
10. Describe how suppliers are selected for external audits.

MATERIALS

The following materials are required to support this module.

1. Copies of companies' procedures for audit programs (internal or external).
2. Reference copy of ANSI N45.2.12 (optional)
3. Reference copy of ANSI N45.2 and ANSI N18.7 (optional).

PROCEDURES

1. As requested in Exercise 1 of this module, obtain from your instructor a copy of a company's procedure for QA audits. Compare the procedure with this module to determine if the procedure (a) meets the objectives of an audit program (b) contains the essential elements of an audit program, and (c) provides for preparation, performance, reporting, and follow-up for specific audits. Prepare a report of findings of this evaluation in the format suggested in this module for audit reports.
2. As requested in Exercise 2 of this module, plan for and perform an audit of a subject assigned by the instructor. Include in the planning the preparation of an audit check list, team orientation if teams are assigned, and notification to the activity to be audited. Include in the performance of the audit preaudit and postaudit conferences. Prepare a report of the audit and submit it to the instructor.

DATA TABLE

Not applicable.

REFERENCE MATERIALS

GPO, Code of Federal Regualtions, Title 10, Parts 0 to 199, U.S. Government Printing Office, 1978

NRC, Regulatory Guide 1.144, Auditing of Quality Assurance Programs for Nuclear Power Plants, U.S. Nuclear Regulatory Commission, 1979

ASME, Quality Assurance Program Requirements for Nuclear Facilities, ANSI N45.2, The American Society of Mechanical Engineers, 1977

ASME, Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants, ANSI N18.7, The American Society of Mechanical Engineers, 1976

ASME, Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants, ANSI N45.2.12, The American Society of Mechanical Engineers, 1977

ASME, Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants, ANSI N45.2.23, The American Society of Mechanical Engineers, 1978

Juran, J.M., Quality Control Handbook, McGraw-Hill, 1974

Johnson, L. Marvin, Quality Assurance Program Evaluation, Stockton Trade Press, Inc, 1970

Match the source document with its description by placing the letter from the right hand column adjacent the document description in the left hand column.

	Description	Document
____ 1.	Gives specific, detailed requirements for an audit system.	a. 10CFR50, Appendix B
____ 2.	Provides criterion by which licensee audit programs are judged.	b. ANSI N45.2
____ 3.	Standard for quality assurance programs for Operations Phase which includes audit program requirements.	c. ANSI N45.2.12
____ 4.	Standard for quality assurance program for the design and construction phase which includes audit program requirements.	d. ANSI N18.7

Answer the following questions or furnish information requested as appropriate:

5. State five objectives of the QA audit program.

6. Describe the organizational relationship between auditors and activities being audited.

7. Briefly describe the scope of training and experience necessary for qualification as an auditor.

8. Name five factors upon which qualification as lead auditor is based.

9. Differentiate between internal audits and external audits.

10. State seven essential elements of the audit system and briefly describe the basis for each.

11. Briefly describe how a listing of suppliers subject to external audits is developed and maintained. Include four characteristics of suppliers which result in placing suppliers on the listing.

12. Briefly describe two methods of developing a listing of subjects which are to be audited by internal audits.

13. Name five factors considered in the development and maintenance of internal and external audit schedules.

14. Describe how skills and qualifications apply to the selection of audit team members.

15. Name five provisions of companies policies for the conduct of any audit.

16. Name three major tasks associated with preparation for a specific audit.

17. State the purpose of audit check lists.

18. Briefly describe how an audit team prepares for conduct of an audit.

19. Briefly describe the accomplishments of a preaudit conference with the organization to be audited.

20. What should an auditor do if a very significant deficiency is found and why?

21. Briefly describe the accomplishments of a postaudit conference with the audited organization.

22. Name six types of information contained in the audit report.

23. Briefly describe the postaudit followup by the audited organization.

24. Briefly describe the postaudit follow-up by the auditing organization.